DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Sun Nuclear Corporation
% Mr. James Luker
Regulatory Affairs Consultant
2640 Nobility Avenue
MELBOURNE FL 32934

December 5, 2014

Re: K142142
Trade/Device Name: Quality Reports, Model 1216
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: November 5, 2014
Received: November 10, 2014

Dear Mr. Luker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142142

Device Name
Model 1216 Quality Reports

Indications for Use *(Describe)*
Model 1216 Quality Reports is intended for quality assessment of radiotherapy treatment plans and the radiotherapy treatment planning process.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

SUN NUCLEAR corporation

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Section 5 – 510(k) Summary

Provided in accordance with 21 CFR 807.92 (c)

1 General Provisions

Date Prepared:

August 2, 2014

Submitted by:

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Classification Name:

21 CFR § 892.5050 IYE Medical charged-particle radiation therapy system
Class II

Common Name:

Oncology Information system

Proprietary Names:

Model 1216 Quality Reports

Establishment Registration Number:

1038814

Classification:

Regulation Number: 21 CFR 892.5050
Name: Medical charged-particle radiation therapy system, dosimetric quality control system
Product code: IYE

Predicate Device(s):

Model Name:	MOSAIQ Release 2.50
Common Name:	Oncology Information System
510(k) #	K123230
Manufacturer:	IMPAC Medical Systems, Inc.
Submitted:	November 6, 2012

Model Name:	MOSAIQ Release 2.40
Common Name:	Oncology Information System
510(k) #	K120067
Manufacturer:	IMPAC Medical Systems, Inc.
Submitted:	January 9, 2012

2 Description and Use:

Model 1216 Quality Reports is a multi-functional information and data management software application intended to be used by trained clinicians who are familiar with radiation therapy, such as medical physicists, medical dosimetrists, and radiation oncologists.

Model 1216 Quality Reports receives DICOM data from Treatment Planning Systems (TPS) which are capable of providing such data. The data may include images, radiation therapy (RT) objects such as RT Plan, RT Structure Set and RT Dose. The user may also capture data through manual input.

The application allows the user to:

- Create reports and charts which may be sent to the institution's Electronic Medical Record (EMR) system.
- Measure quality with standardized metrics that are based on the institution's chosen standards.
- Capture information from the clinical team during pre-treatment planning.
- Establish benchmark and progress data to demonstrate continuous improvement.
- Audit the Dose Volume Histogram (DVH) from the TPS.
- Facilitate quantitative review of the estimated dose via a single DVH metric.
- Customize and save a library of non-dosimetric plan parameters and compare them against user defined constraints.
- Track plan quality scores over time to assess performance and provide the basis for measuring continual improvement.

3 Intended Use Statement:

Model 1216 Quality Reports is intended for quality assessment of radiotherapy treatment plans and the radiotherapy treatment planning process.

4 Technological Characteristics

As with the predicate devices, Model 1216 Quality Reports software runs on a standard PC running a Windows Operating System (OS). The complexity of DICOM data and the sheer data volume in images and DICOM RT objects (notably RT Structure Sets and RT Doses) demands high performance computer processing and memory. The software holds all vital data in memory during each analysis and report generation session to ensure high performance to optimize the user experience, and thus there are special requirements for the machine(s) on which the software is installed.

System Recommendations

- Operating Systems Supported: Windows 7 (32- or 64-bit), Windows 8 (32- or 64-bit), and Windows Server 2008, 2008 R2, and 2012
- CPU: 2.4+ GHz
- CPU: Multi-core processor (4+ cores, 8+ threads)
- Hard drive space: Software components fully installed require only ~20 MB, but storage requirements for voluminous patient data and archives are much larger but will vary clinic-to-clinic. A minimum of 900 GB hard drive is suggested with larger drives for DICIOM archives.
- Memory (RAM): 2+ GB x number of cores (e.g. 8+ GB for 4 cores)
- Display Resolution: 1920 x 1080 screen resolution, 24- or 32-bit color depth.

5 Performance Data and Comparison with Predicate

As with the predicate device, no clinical trials were performed for Model 1216 Quality Reports. Testing was limited to Bench testing using simulated clinical workflows.

Verification tests were written and executed to ensure that the system was working as designed. Pass/fail criteria were used to verify requirements and to ensure that risk mitigations functioned as intended. Regression tests were performed.

6 Summary

Model 1216 Quality Reports is deemed substantially equivalent to the predicate devices due to the similarities in function, technology, and performance. The intended use, performance testing, safety and effectiveness reviews demonstrate that Quality Reports is as safe, as effective, and performs as well as the predicate device. The minor technological differences between Model 1216 Quality Reports and the predicate devices do not raise new types of safety or effectiveness questions.